Exactech®

2320 NW 66TH COURT
GAINESVILLE, FL 32653
352-377-1140
FAX 352-378-2617

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JUN 21 2005

Exactech® AcuMatch 12/14 Press-Fit Femoral Stems

510(k) Summary of Safety and Effectiveness
Special 510(k)

Trade or proprietary or model name(s):

AcuMatch 12/14 P-Series Press-Fit Plasma Femoral Stems
AcuMatch 12/14 L-Series Press-Fit Femoral Stems

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K041906	AcuMatch 12/14 P-Series Plasma Press-Fit Femoral Stems AcuMatch 12/14 L-Series Press-Fit Femoral Stems	Exactech, Inc.

INDICATIONS

All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

AcuMatch® P-Series and AcuMatch® L-Series press-fit femoral stems are intended for press-fit fixation.

Press-fit components without hydroxyapatite (HA) coating may also be used with bone cement at the discretion of the surgeon.

Special 510(k) Modifications

The AcuMatch 12/14 Press-Fit femoral stems were modified from the predicate as follows:

- The geometry of the insertion hole feature was modified from an oblong slot to an oblong slot with threads (P-Series only).
- The tolerance of the 12/14 taper threadform geometry was expanded.
- Collared 12/14 P-Series Press-Fit Stem option was added.

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510(k) Summary of Safety and Effectiveness
Special 510(k)

AcuMatch 12/14 Press-Fit Femoral Stems

AcuMatch 12/14 Press-Fit femoral stems are composed of titanium alloy (ASTM F1472), have a trapezoidal cross-sectional geometry and distal taper.

- 12/14 P-Series model has a plasma-spray surface enhancement.
- 12/14 L-Series model has a corundum finish.

Both models have a hydroxyapatite (HA) coating option. The femoral stems are intended for press-fit applications but models without the HA coating may be used with bone cement at the discretion of the surgeon.

Conclusion:

Testing and engineering evaluations were conducted to verify that the performance of the new Exactech AcuMatch 12/14 Press-Fit Femoral Stem components would be adequate for anticipated *in vivo* use. This includes empirical testing and engineering analyses. Based on successful results we conclude that the proposed devices are substantially equivalent to Exactech's predicate femoral stems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 21 2005

Ms. Maritza Elias
Regulatory Representative
Exactech, Inc.
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K051335
Trade/Device Name: Exactech Acumatch 12/14 Press-Fit Femoral Stems
Regulation Number: 21 CFR 888.3353, 888.3350
Regulation Name: Hip joint metal/cemented/polymer semi-constrained cemented or non-porous uncemented prosthesis; Hip joint metal/polymer semiconstrained cemented prosthesis
Regulatory Class: II
Product Code: JDI, LWJ, MEH, LZO
Dated: May 17, 2005
Received: May 23, 2005

Dear Ms. Elias:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech®, Inc.

Exactech AcuMatch 12/14 Press-Fit Femoral Stems

Indications for Use

510(k) Number: K051335

INDICATIONS

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Press-fit components without hydroxyapatite (HA) coating may also be used with bone cement at the discretion of the surgeon.

Prescription Use ___X___ **or** **Over the Counter Use** _____

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K051335